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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on August 8, 2002

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days; whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-4, 6-11, 15-19, & 21-40 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-4, 6-11, 15-19, & 21-40 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-11, 15-17, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee. Dietrich et al teaches a device as claimed except for the transparent plug; self sealing membrane and a laser which allows the patient to move about freely. Chen et al teach an indwelling PDT device including multiple lumens, a plug and a valve, and irradiation over a long period of time. Lee teaches the desirability of employing self sealing membranes and shows a funnel-shaped opening. It would have been obvious to employ the self sealing membranes of Lee and the plugs claimed since these would enable the fluid to be retained in the balloon more easily and prevent the excursion of blood or other fluids and to provide low dosage PDT over a longer period of time, since this is more effective against the diseased tissue, as taught by Chen et al, or alternatively to form the spherical radiator of Chen et al as a balloon, since this enables more even illumination in the event the cavity is larger than the radiator, since the balloon can be inflated and would further allow less traumatic removal and insertion of the device, since the balloon can be deflated and in either case to provide a funnel shaped entrance, as shown by Lee since this would tend to guide the inserted device into the passage, which is notorious in the art, thus producing a device such as claimed.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee as applied to claims 1-4, 6-11, 15-17, 19, and 21 above, and further in view of Hayman et al. Hayman et al teach the desirability of combining PDT and

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radiation treatment. It would have obvious to the artisan of ordinary skill to employ a radioactive wire, since this is a useful adjunct to PDT, as taught by Hayman et al thus producing a device such as claimed.

Claims 22-31, and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee. The teachings of Dietrich et al, Lee and Chen et al are, asset forth above set forth above, and additionally the total implantation of the irradiator and the use of PDT on breast cancer by Chen et al. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings and provide the stated modifications for the reasons set forth above to produce a method such as claimed and to prolong the treatment over the course of months or a year, since some cancers are very difficult to irradiate, thus producing a method such as claimed.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich et al in combination with Chen et al and Lee as applied to claims 22-31 and 33-40 above, and further in view of Hayman et al. The teachings of Hayman and the motivations for combination thereof are essentially those set forth above. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings to produce a method such as claimed.

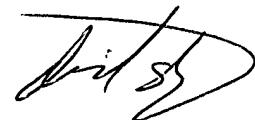
Applicant argues that the self healing membrane, the funnel shaped insert and the implantable optical coupler are not taught by the applied art. The examiner notes the reference to Lee which specifically teaches a self healing membrane to prevent the outflow of fluids from the catheter and shows an insert with a funnel shape coupling to the lumen. The examiner notes that

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the shape is readily perceivable to one having ordinary skill as guiding material towards the reduced diameter portion of the element in the same manner as the walls of a funnel do and in any case that the configuration is notorious for providing this function. The fluid between the balloon in either Chen et al or Dietrich et al reads on applicants "implantable optical coupler".

Applicant's arguments with respect to claims 1-4, 6-11, 15-19, and 21-40 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.



DAVID M. SHAY
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David Shay:lf
November 12, 2002